



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

AUG 20 1999

1047 '99 AUG 23 P1:16

Ms. Joanne McCall Magness  
P.O. Box 500, 572 Baltimore Street  
Charlestown, Maryland 21914

Dear Ms. Magness:

Thank you for your letter of April 19, 1999, addressed to Senator Barbara A. Mikulski, concerning the petition for a performance standard for *Vibrio vulnificus* in shellfish filed with the Food and Drug Administration (FDA or the Agency) by the Center for Science in the Public Interest. Senator Mikulski has asked us to respond directly to you. As you may know, FDA published a request for comments on this petition in the Federal Register of January 21, 1999. We have enclosed a copy for your reference.

You oppose the petition and believe that it will have adverse economic effects on the shellfish industry. You recommend that FDA work with the Interstate Shellfish Sanitation Conference on this matter. We appreciate you bringing your comments to our attention and we have entered them into the Administrative Record for this petition. Your comments will be reviewed in the Agency's deliberations on this petition.

We trust this information responds to your concerns.

Sincerely,

Melinda K. Plaisier  
Interim Associate Commissioner  
for Legislation

Enclosure

Federal Register, January 21, 1999

98P-0504

A  
C268 /Ans

Page 2 - Ms. Joanne McCall Magness

cc: The Honorable Barbara A. Mikulski  
United States Senate  
Washington, D.C. 20510-4704

Dockets Management Branch ✓  
(Docket No. 98P-0504)

BARBARA A. MIKULSKI  
MARYLAND

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TDD: (202) 224-5223

United States Senate  
WASHINGTON, DC 20510-2003

July 29, 1999


Ms. Diane Thompson  
Assoc. Commissioner for Legislative Affs.  
Dept. of Health & Human Services  
Food and Drug Administration  
5600 Fishers Ln. 1555 Parklawn Bldg.  
Rockville, Maryland 20857

Dear Diane:

I am writing to request your consideration of the attached correspondence from Ms. Joanne Magness. Please respond directly to Ms. Magness and send a copy to Ms. Emily Gilbert of my staff. If you have any questions, please call Ms. Gilbert at (202) 224-4654.

Thank you for your assistance.

Sincerely,



Barbara A. Mikulski  
United States Senator

BAM:efg  
Enclosure

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99-5308

# JOANNE MCCALL MAGNESS

April 19, 1999

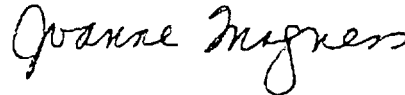
William K. Hubbard  
Dockets Management Branch (HFA)  
5630 Fishers Lane Room 1061  
Rockville, MD 20852

Re: Docket Number 98P-0504

Dear Mr. Hubbard:

Before accepting the petition, brought by the Center for Science in the Public Interest, to require post-harvest treatment for all shellfish grown in areas with detectable levels of *Vibrio vulnificus*, I urge that further research be conducted to develop a sound scientific basis on which to base policy related to the sale of raw shellfish. I further implore the FDA to refer this matter to the Interstate Shellfish Sanitation Conference (ISSC) for continued deliberation. The ISSC has proven to be the appropriate group to develop standards and regulations for the Shellfish Industry.

Sincerely,



JOANNE MCCALL MAGNESS

cc: Senator Paul Sarbanes  
Senator Barbara Mikulski  
Congressman Wayne Gilcrest

P.O. BOX 500, 572 BALTIMORE STREET • CHARLESTOWN, MARYLAND • 21014  
TELEPHONE: 410-287-5949

# JOANNE MCCALL MAGNESS

April 19, 1999

Senator Paul Mikulski

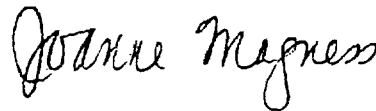
Re: Docket Number 98P-0504

Dear Senator Mikulski:

I urge you to support the Pacific Coast Oyster Growers Association's (PCOGA) position to refer the matter of post-harvest treatment for all shellfish grown in areas with detectable levels of *Vibrio vulnificus* to the Interstate Shellfish Sanitation Conference for continued deliberation. The PCOGA predicts that as many as 75% of shellfish growers could be pushed out of business across the nation if the Food and Drug Administration accepts the petition of the Center for Science in the Public Interest. This could have dire consequences for the watermen of Maryland.

The Interstate Shellfish Sanitation Conference (ISSC) has proven to be the appropriate group to develop standards and regulations for the Shellfish Industry. I implore you to recommend the FDA refer this matter to them for continued deliberation and provide the funding for research necessary to develop appropriate criteria for establishing public health policy.

Sincerely,



JOANNE MCCALL MAGNESS

Attachment: Letter to William K. Hubbard

Post-it® Fax Note	7671	Date	4/19	# of pages	2
To	MIKULSKI	From	MAGNESS		
Co./Dept.		Co.			
Phone #		Phone #	410-287-5949		
Fax #	202-224-8858	Fax #			

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